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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/423,943 03/08/00 SAMPATH

K 00960-570

EXAMINER

HM12/0130

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ANDRES, J

ART UNIT

PAPER NUMBER

1646

11

DATE MAILED:

01/30/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/423,943

Applicant(s)

SAMPATH ET AL.

Examiner

Janet L Andres

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-122 is/are pending in the application.
- 4a) Of the above claim(s) 6, 7 and 29-122 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

Priority

1. Applicant's claim to priority based on PCT/US98/10909, filed May 29, 1998 is acknowledged.

Election/Restrictions

2. Applicant's election of Group 1, claims 1-28, without traverse is acknowledged. Applicant's species election of OP-1 morphogens and neural tissue-type species is acknowledged. Applicant has traversed the species election on the basis that the claimed peptides are not individually distinct and independent, but are in fact members of the same superfamily of proteins, "morphogens". The examiner disagrees that these proteins are so related as to not be individually distinct and independent, since the included proteins have many different and even opposing functions, and thus do not share a common utility. However, the examiner agrees that a method of evaluating the morphogenic activity of these proteins does not require consideration of the distinctive functions and characteristics of each, and the requirement for election of a specific morphogen is withdrawn. Applicant has not provided a basis for traversal of the requirement to elect a tissue type, and this species election is maintained. Claims 1-5 and 8-28 are under consideration in this application. Claims 6-7 are withdrawn from consideration as being drawn to a non-elected invention. Claims 29-122 are withdrawn from consideration as being drawn to a non-elected invention. The restriction requirement is made FINAL.

Specification

3. The disclosure is objected to because of the following informalities: There is an underlined space with no words on page 3, line 24.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-5, 12-14, 20, and 23-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Rueger et al., WO 94/03200.

Rueger et al. teaches nerve regeneration induced by morphogens, including OP-1, BMPs, and other members of the TGF-beta superfamily (pages 18-23), including consensus sequences (pages 27-31) as well as molecules having 70% homology to the C-terminus of OP-1 (p. 39). Rueger et al. further specifically teaches methods of evaluation of candidate molecules on p. 45 and pages 99-100. *In vivo* models in which a lesion is created and morphogens applied are taught on pages 90-93, which disclose sciatic nerve repair as well as optic nerve repair. Methods of administration including oral administration are taught on pages 17 and 55-58.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
7. Claims 8-11, 15-19, 21, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rueger et al., WO 94/03200. Rueger et al. teaches as set forth above but fails to teach evaluation in compromised animals, as claimed in instant claims 8-11, 21 and 22, or at specified times, as claimed in claims 15-19. However, it would have been obvious to one of ordinary skill to evaluate treatment parameters such as time of administration and administration to compromised animals. Optimization of treatment protocols is art standard: Benet and Sheiner, for example, teach conditions including age and disease as affecting drug administration (in Goodman and Gilman's The Pharmacological Basis of Therapeutics, 6th edition, 1980, p. 1685). Further, Rueger et al. teaches evaluation of administration "e.g. just prior to the operation, concomitant with the operation, or at specified times after the operation" in the optic nerve model (p. 93). Thus it would have been obvious to one of ordinary skill to evaluate morphogens using the method of Rueger et al. at different times and in different disease states; one of ordinary skill would have been motivated to do so because Rueger et al. explicitly suggests different time points, and because altered effects in disease states are well known in the art, as taught by Benet and Sheiner.

8. Claims 1-5 and 8-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al., WO 95/05846.

Wang et al. teaches the use of BMPs to repair neural defects in mammals by administration at the site of a “neural depletion, damage, or defect” (page 2, lines 8-12). Wang et al. further teaches administration topically, adsorbed to a matrix, and intravenously (page 5, lines 26-30, page 6, lines 1-10, page 8, lines 19-30). *In vivo* evaluation of BMP-2 is taught using a rat model in which the sciatic nerve is severed and the protein is applied adsorbed to a collagen sponge. Success is evaluated by electrical return of function and by histological analysis (page 16, lines 11-30). Thus Wang et al. teaches evaluation of the morphogenic activity of BMP-2 in a neural defect by local administration and evaluation of new tissue formation. Wang et al. further teaches intravenous administration of BMPs, as set forth above, thus encompassing the limitation of “distal administration” of claims 2 and 4. Wang et al. does not explicitly teach a method of evaluation of morphogens *per se*. However, it would have been obvious to one of ordinary skill in the art to apply the method taught by Wang et al. for the evaluation of BMP-2 to evaluate other morphogens. One of ordinary skill would have been motivated to do so because Wang et al. teaches other BMPs as inducers of neuronal growth (page 2, lines 4-19) and teaches that the BMPs are members of a larger family of related proteins (page 1, lines 16 and 17).

Wang et al. further fails to explicitly teach oral administration, evaluation by administration to compromised animals, or evaluation of administration at specified times after the creation of the defect. However, it would have been obvious to one of ordinary skill to evaluate dosage strategies. Such evaluation is standard in the development of therapeutic agents, as discussed above, and further, Wang et al. teaches modification of the “therapeutically

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effective amount” based on “condition, body weight, sex and diet of the patient, the severity of the condition, time and method of administration and other clinical factors” (page 7, lines 6-14).

Thus, since Wang et al. teaches BMPs as neuronal regeneration factors and further teaches the necessity for modification of therapy based on clinical factors, it would have been obvious to one of ordinary skill to evaluate morphogens as instantly claimed.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 2 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims are drawn to “distal” administration, but depend from claims that are drawn to “systemic” administration. Thus one of skill would not know what type of administration applicant intended these claims to encompass.

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 305-3014 or (703) 308-4242.

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Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.
January 29, 2001


YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600